UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,997	07/26/2001	Donald W. Petersen	06317-038002	1532

826 7590 12/14/2004

ALSTON & BIRD LLP
BANK OF AMERICA PLAZA
101 SOUTH TRYON STREET, SUITE 4000
CHARLOTTE, NC 28280-4000

EXAMINER	
WITZ, JEAN C	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 12/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/915,997	PETERSEN ET AL.	
	Examiner	Art Unit	
	Jean C. Witz	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *43-60 and 62-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *43-60 and 62-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed October 13, 2004 with respect to the claims of record have been considered but are moot in view of the new ground(s) of rejection.

2. The finality of the previous office action is withdrawn in view of the new grounds of rejection.

Claim Rejections - 35 USC § 102/103

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 43-47, 49-60, 62-68 are rejected under 35 U.S.C. 102(b) as being anticipated by, or in the alternative, under 35 U.S.C. 103(a) as obvious over Yim et al. (U.S. Patent 5,385,887).

The instant claims recite a bone graft substitute composition comprising 100 parts by weight of calcium sulfate hemihydrate, about 1 to about 10 parts by weight of a

plasticizing substance and an aqueous mixing solution in a form suitable for use as a bone graft substitute.

Yim et al. (U.S. Patent 5,385,887) disclose a bone graft substitute comprising calcium sulfate hemihydrate, a plasticizing substance within the scope disclosed and claimed by Applicants and an aqueous mixing solution. See col. 8, lines 15-30, disclosing a composition of calcium sulfate hemihydrate, osteogenic proteins in aqueous solution and a protein-sequestering agent (defined at col. 7, lines 26-45 to be cellulosic compounds as recited in claims 44-47 and 49). Therefore, the components of the claims are all found in the composition of Yim et al. Therefore, the only determination to be made is whether the amounts as claimed are the same as the amounts disclosed. Yim et al. disclose a composition comprising approximately 0.5 to 2 grams of osteogenic protein per 10-20 grams of calcium sulfate hemihydrate in approximately 3 ml of water. The claim language recites all amounts in parts by weight which is dependent upon the total components and total weight of the components. With the open claim language, there is no limitation to the other ingredients other than the plasticizing substance and the mixing solution. However, based upon the composition containing at least the three claimed ingredients, the percent ranges of calcium sulfate hemihydrate would appear to be around 57-85%, the percent ranges of the plasticizing substance would appear to be about 1-8% of plasticizing substance and the percent ranges of the mixing solution would appear to be 16-37%. Yim et al. teach that cellulosic protein sequestering agent is preferably present in a concentration of about 2-10%, which overlaps the calculated range. Yim et al. teach that preferred

compositions contain 0.5-2 grams of osteogenic proteins per 10 – 20 grams calcium sulfate hemihydrage in approximately 3 ml of water. One milliliter of water weighs 1 gram. These formulations may include the protein-sequestering agent as previously described in amounts previously described. The calculated percent range of calcium sulfate hemihydrate in this preferred composition is 66-85% and the calculated percent range of the mixing solution is about 12-22%. These ranges overlap the ranges calculated for the claimed invention. When a cellulosic protein sequestering agent is included, these ranges would change somewhat; however, it appears clear that the amounts taught in the reference, in the least, overlap the ranges claimed for the same ingredients. "[W]hen, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is anticipated' if one of them is in the prior art." Titanium Metals Corp. v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (citing In re Petering, 301 F.2d 676, 682, 133 USPQ 275, 280 (CCPA 1962)) (emphasis in original).

In the alternative, since the physical properties of both the calcium sulfate hemihydrate and the plasticizing (cellulosic protein sequestering) substances are well known, it would have equally been well within the skill of the practitioner at the time the invention was made to engage in a reasonable and not undue amount of experimentation to determine a desired recipe for a bone graft composition containing calcium sulfate hemihydrate, a plasticizing substance as disclosed and the amount of wetting solution required, particularly since the amounts claimed are either well within the ranges disclosed or extremely close. It is also noted that the patent uses the term

"approximately" which indicates that there is at least some leeway in the amounts taught to be effective.

With regard to claim 60, the claim recites a bone graft substitute composition consisting essentially of calcium sulfate, a mixing solution and a plasticizing substance. The transitional phrase "consisting essentially of" is deemed to limit the scope of a claim to the specified components in the claims but also allows inclusion of "those [components] that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). In this case, the prior art hydraulic fluid required a dispersant which appellants argued was excluded from claims limited to a functional fluid "consisting essentially of" certain components. In finding the claims did not exclude the prior art dispersant, the court noted that appellants' specification indicated the claimed composition can contain any well-known additive such as a dispersant, and there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention. The prior art composition had the same basic and novel characteristic (increased oxidation resistance) as well as additional enhanced detergent and dispersant characteristics.). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." If Applicants contend that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or

components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989). In this case, the instant specification teaches that other ingredients may be included with the claimed composition including bone morphogenic (osteogenic) proteins and any number of other ingredients such as listed at page 4 of the specification. Therefore, the osteogenic proteins of Yim et al. do not affect the basic and novel characteristics of the invention set forth in claim 60 and the claim language "consisting essentially of" is not interpreted to exclude the osteogenic proteins of Yim et al.

Claims 43-45, 54-56, 58-60, 62-66 and 68 are rejected under 35 U.S.C. 102(b) as being anticipated by, or in the alternative, under 35 U.S.C. 103(a) as obvious over GB 999,487.

The phrase "bone graft substitute" is deemed to be a recitation of intended use that fails to confer patentability to an old composition. The patent teaches a composition consisting of calcium sulfate hemihydrate mixed with water and methyl sodium carboxymethylcellulose within the amount claimed. See Example 1. The amount of carboxymethylcellulose disclosed (0.4 parts) and the amount of aqueous mixing solution (44 parts) is deemed to fall within the limits of the claimed ranges of the plasticizing substance (about 1 to about 10 parts – claim 43, about 1 to about 7 parts – claim 54 or about 2 to about 6 parts – claim 55) and within the limits of the claimed ranges of the aqueous missing solution (about 20 to about 40 parts – claim 56) because, since one of the objects of the present invention is to provide a bone graft

substitute composition that can be mixed into a paste and then loaded into a syringe and ejected for an extended period of time (e.g., more than ten minutes). The composition defined in Example 1 forms a paste that takes 37 minutes to set. Therefore, since Applicants did not explicitly place a definition of the term "about" in the specification, the broadest reasonable interpretation of this term must be inferred from the specification and since the specification sets forth the desired characteristics of the composition resulting from the combination of the claimed ingredients and the prior art composition meets these characteristics using an amount of the plasticizing agent that is close to one end of the range denoted to extend outside of the explicit values by the use of the term "about", the referenced prior art composition is deemed to anticipate the cited claims.

In the alternative, since the specification sets forth the desired characteristics of the composition resulting from the combination of the claimed ingredients and since the physical properties of both the calcium sulfate hemihydrate and the plasticizing (cellulosic protein sequestering) substances are well known, it would have been well within the skill of the practitioner at the time the invention was made to engage in a reasonable and not undue amount of experimentation to determine a desired recipe for a set-retarded calcium sulfate hemihydrate composition having a paste consistency and extended set time containing calcium sulfate hemihydrate, a plasticizing substance as disclosed and the amount of wetting solution required, particularly since the amounts recited in the prior art are either well within the claimed ranges or very close to claimed amounts.

With regard to claim language reciting "a form suitable for use as a bone graft substitute", the prior art composition meets this limitation. While it is understood that the prior art composition would most probably have been used in construction, all terms must be given broadest reasonable interpretation consistent with the specification. The term "suitable" is not expressly defined in the specification. Broadest reasonable interpretation of the term "suitable" is "appropriate for a given purpose". The composition of GB 999,487 is clearly appropriate for the purpose of a bone graft substitute since it contains the exact same ingredients are the claimed bone graft substitute. While particular embodiments of the composition would be preferred, such as the use of sterile water as the aqueous mixing solution, such embodiments are not found in the cited claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (571) 272-0927. The examiner can normally be reached on 6:30 a.m. to 4:00 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jean C. Witz
Primary Examiner
Art Unit 1651